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| | | | EXAMINER CHAPMAN, GINGER T | |
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

mail@ipcounselors.com

Office Action Summary

Application No.

10/811,055

Applicant(s)

CLINE, JOHN B.

Examiner

Ginger T. Chapman

Art Unit

3761

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 April 2010.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 35-38 and 40-60 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 35-38 and 40-60 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 26 March 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB06)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Status of the claims

1. Claims 35, 59 and 60 are amended, 35-38 and 40-60 are pending in the application.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

1. Claims 35-38 and 40-60 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-9 and 11-17 of copending Application No. 11/430,542. Although the conflicting claims are not identical, they are not patentably distinct from each other because the '542 application claims means for preventing passage of liquid and solid material through a stoma, adhesive means surrounding a stoma and pressurizable means for pressing the preventing means against a stoma

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections – 35 USC § 103

The following is a quotation of 35 U.S.C. § 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 35-38, 40, 42-44, 46, 47, 50-55, 59 and 60 are rejected under 35 U.S.C. § 102(b) as being anticipated by Kawasaki et al (US 5,433,724) in view of Wagner (US 6,071,268) in view of Lloyd (US 4,475,908) and further in view of Barakat (US 2004/0087917 A1).

Regarding claims 35, 59 and 60, Kawasaki teaches a device (1) capable of sealing a stoma to control the passage of liquid and solid waste material through the stoma, said device (1) being situated entirely externally to the body and comprising recess defining means (4);

adhesive (14, 15) surrounding and enclosing a stoma capable of securing said recess defining means (4) to the body such that the recess defining means forms a seal with the body completely surrounding and enclosing the stoma (A);

and stoma covering means (5), situated externally to the body, over the stoma (A), within said recess defining means (4), and comprising a continuous, uninterrupted member adapted to prevent passage of liquid and solid waste material through the stoma (A) when pressed against the stoma (A), said recess defining means (4) defining, with said stoma covering means (5), a chamber, said chamber comprising a fluid entrance port (7) and being situated over said stoma covering means (5), said chamber being pressurizable with fluid through said fluid entrance port (7) to press said stoma covering means (5) against the stoma and further comprising means for sealing (6) said fluid entrance port to prevent the fluid from escaping said chamber after it is pressurized (col. 7, lines 10-15; col. 9, lines 20-33)(see figures 2 & 4, *infra*).

Regarding the interpretation of "stoma," a "stoma" is herein construed to mean a surgically created artificial opening in a human patient, it is not limited to an intestinal opening. See *Medicinenet.com* definition of stoma. See also, *Merriam Webster's* definition of "stoma." For example, tracheal stomas and ureteral stomas are well known in the art. Applicant's specification does not specifically set forth a definition of "stoma" that precludes this interpretation. The claims must be given their broadest reasonable interpretation MPEP § 2111.

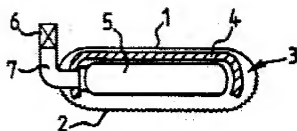


FIG. 2

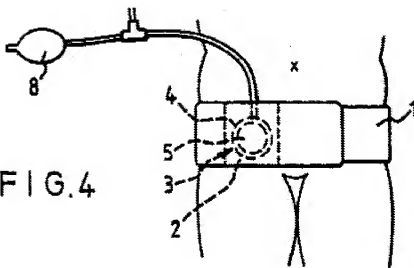


FIG. 4

Kawaski discloses the claimed invention except for the adhesive completely surrounds and encloses the stoma. Kawaski provides motivation for a seal. As best depicted in Figures 2, 3, 5-12, Wagner teaches providing seal completely surrounding and enclosing a stoma on all sides. Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the seal of Kawaski as taught by Wagner since Wagner states, at c. 4, ll. 29-31, that the benefit of this design is that it provides a gentle sealing force around the stoma which is sufficient to provide a seal against leakage but avoids stomach, i.e. skin irritation.

Kawasaki in combination with Wagner discloses the claimed invention except for the adhesive means comprising a continuous, uninterrupted adhesive layer. Kawasaki discloses adhesive (14, 15) surrounding and enclosing a stoma capable of securing said recess defining means (4) to the body such that the recess defining means forms a seal with the body completely surrounding and enclosing the stoma (A) thus providing motivation for forming a seal to prevent leakage, Wagner teaches providing a seal to prevent leakage, thus providing motivation for a seal around the stoma capable of preventing leakage.

Lloyd, at column 2, lines 30-39 teaches that such adhesive seals can be provided in ostomy devices in a variety of manners, and in particular at lines 32-34 that the adhesive means can comprise a continuous and therefore uninterrupted layer of adhesive. Lloyd also teaches microporous and macroporous adhesive layers, thus contemplating and teaching that both continuous and discontinuous adhesive layers are both suitable for providing seals on ostomy devices.

Lloyd teaches a foam substrate that conforms to a stoma to provide to provide a seal and further teaches at c. 2, lines 40-45, that continuous layers of adhesive can be formed on open such surfaces as foams by providing a substrate that will support a continuous layer of adhesive to the foam sealing structure, thus providing motivation and a manner of ways to achieve a continuous, uninterrupted layer of adhesive to thereby provide a continuous seal for an ostomy device that will conform the wearer's stoma. Therefore, in view of the teachings of Lloyd, it would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the device of Kawasaki with adhesive means comprising a continuous, uninterrupted layer situated between and in direct contact with the recess defining means and the

skin surrounding the stoma since Lloyd teaches that this can be accomplished in a manner of ways to obtain the benefits of a leakage preventing seal.

Kawasaki discloses the claimed invention except for the continuous, uninterrupted adhesive layer situated between and in direct contact with said recess defining means and the skin surrounding the stoma. Barakat, which is analogous art directed to solving the same problem of providing adhesive for ostomy devices that can maintain contact, teaches, at paragraphs [0045-0046] the adhesive continuous, uninterrupted adhesive layer situated between and in direct contact with said recess defining means and the skin surrounding the stoma. Barakat teaches the adhesive having a constant thickness / caliper or calliper for all adhesive coated layers and additionally further discloses embodiment wherein the adhesive can be in varying calipers and also in varying patterns. Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the adhesive of Kawasaki in the claimed configuration as taught by Barakat since Barakat states, at paragraphs [0041 and 0047], that the benefit of providing the adhesive in this manner is that it allows the adhesive to adapt to the contours of the stoma for secure attachment during use thereby minimizing leakage of bodily waste fluids from the ostomy flanges in use thereby providing a cleaner more sanitary ostomy device.

Regarding claim 36, Kawasaki teaches that means (5) is a flexible membrane (col. 5, lines 1-15).

Regarding claim 37, Kawasaki teaches that stoma covering means (5) has an edge that is fixed within the recess defining means (4).

Regarding claims 38, 42 and 46, Kawasaki teaches a flexible, external pressurizing means (8).

Regarding claims 40 and 43, Kawasaki teaches a one-way valve (6).

Regarding claim 44, Kawasaki teaches a gauge (9) that permits an operator to manually limit the pressure applied via pressurizing means.

Regarding claim 47, Kawasaki teaches a tube (7) that can be removed to open a vent.

Regarding claims 50 and 51, Kawasaki teaches removable engaging means (1) capable of engaging recess defining means (4) and adhesive means (14, 15).

Regarding claims 52, 53 and 55, Kawasaki teaches collapsible waste collection means (3, 10, 29) including a pouch.

Regarding claim 54, Kawasaki teaches a waste collecting means (10) connected to the securing means (14, 15).

3. Claim 41 is rejected under 35 U.S.C. § 103(a) as being unpatentable over Kawasaki. Kawasaki does not teach an integral pump.

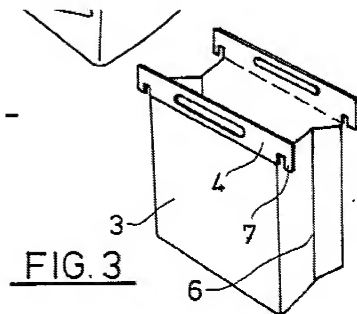
Making what is known in the art to be separable, integral, is not sufficient to patentably distinguish the claimed invention over the prior art. *In re Larson*, 340 F.2d 965, 968, 144 USPQ 347, 349 (CCPA 1965).

4. Claim 56 is rejected under 35 U.S.C. § 103(a) as being unpatentable over Kawasaki (US 5,433,724) in view of Wagner (US 6,071,268) in view of Lloyd (US 4,475,908) in view of Barakat (US 2004/0087917 A1) and further in view of Bergmann *et al.* (DE 43 40 705 A1; hereinafter "Bergmann").

Kawasaki does not disclose expressly that the device can be used with waste collection means having a concertina-like configuration.

Bergmann teaches a waste bag (4) having a concertina configuration (see English language abstract)(see fig. 3, *infra*).

At the time of the invention, it would have been obvious for one of ordinary skill in the art to use the medical waste pouch of Bergmann to dispose of the device of Kawasaki in order to provide a means of conveniently disposing of the device after use.

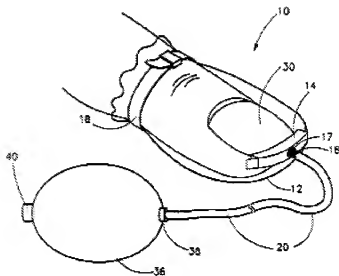


5. Claim 45 is rejected under 35 U.S.C. § 103(a) as being unpatentable over Kawasaki in (US 5,433,724) in view of Wagner (US 6,071,268) in view of Lloyd (US 4,475,908) in view of Barakat (US 2004/0087917 A1) and further view of Berenstein (US 5,795,314 A).

Kawasaki does not expressly disclose a pressure relief valve.

Berenstein teaches a pressure-limiting or relief valve or vent (22)(see fig. 1, *infra*).

Where a claimed improvement on a device or apparatus is no more than "the simple substitution of one known element for another or the mere application of a known technique to a piece of prior art ready for improvement," the claim is unpatentable under 35 U.S.C. § 103(a). *Ex Parte Smith*, 83 USPQ.2d 1509, 1518-19 (BPAI, 2007)(citing *KSR v. Teleflex*, 127 S.Ct. 1727, 1740, 82 USPQ2d 1385, 1396 (2007)). Accordingly, Applicant claims a combination that only unites old elements with no change in the respective functions of those old elements, and the combination of those elements yields predictable results; absent persuasive evidence that the modifications necessary to effect the combination of elements is uniquely challenging or difficult for one of ordinary skill in the art, the claim is unpatentable as obvious under 35 U.S.C. § 103(a). *Ex Parte Smith*, 83 USPQ.2d at 1518-19 (BPAI, 2007)(citing *KSR*, 127 S.Ct. at 1740, 82 USPQ2d at 1396). Accordingly, since the applicant[s] have submitted no persuasive evidence that the combination of the above elements is uniquely challenging or difficult for one of ordinary skill in the art, the claim is unpatentable as obvious under 35 U.S.C. § 103(a) because it is no more than the predictable use of prior art elements according to their established functions resulting in the simple substitution of one known element for another or the mere application of a known technique to a piece of prior art ready for improvement.



Response to Arguments

Applicant's arguments filed 04/08/2010 have been fully considered but they are not persuasive. Applicants' arguments are drawn to the claims as amended and are answered in the rejection of the claims, *supra*, in particular the teachings of Barakat with reference to the adhesive applied in a continuous uninterrupted adhesive layer situated in direct contact with the recess defining means and the skin of the stoma. See also the teachings of Cinelli, cited in the conclusion as relevant art.

The examiner notes that the instant Specification at, *inter alia*, paragraphs [0029-30, 42] and throughout other paragraphs disclose structural features of the claimed pump (see also the rejection with respect to claim 41, *supra*) which would serve to distinguish the claimed invention over the cited art.

Conclusion

2. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.
3. Cinelli (US 6,607,516) at column 8, lines 22-27, teaching adhesive applied in a continuous uninterrupted layer.
4. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ginger T. Chapman whose telephone number is (571)272-4934. The examiner can normally be reached on Monday through Friday 9:30 a.m. to 6:00 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tatyana Zalukaeva can be reached on (571) 272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Ginger T Chapman/
Examiner, Art Unit 3761
07/02/10

/Tatyana Zalukaeva/

Supervisory Patent Examiner, Art Unit 3761